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Name of listed company: Chugai Pharmaceutical Co., Ltd.
Code number: 4519 (1st Section of Tokyo Stock Exchange)
Head office: 1-1, Nihonbashi-Muromachi 2-Chome, Chuo-ku, Tokyo
Chairman & CEO: Osamu Nagayama
Inquiries to: Masahiko Uchida, General Manager,
Corporate Communications Dept.
Tel: +81-(0)3-3273-0881

Judgment Rendered on the Suit for Damages with Regard to the Process Patent Infringement for OXAROL[®] Ointment

July 27, 2017 (Tokyo) -- Chugai Pharmaceutical Co., Ltd. announced that a judgment had been rendered on the suit for damages with regard to Chugai's process patent (Japanese Patent No. 3310301; hereinafter referred to as "Patent") on "OXAROL[®] Ointment 25 µg/g" (hereinafter referred to as "OXAROL Ointment"), a drug for the treatment of keratosis including psoriasis vulgaris.

As announced in "The Supreme Court Rendered Favorable Judgment on Patent-Infringement Lawsuit Regarding OXAROL Ointment" (Press Release Dated March 24, 2017), Chugai has already received a favorable judgment in a lawsuit in which Chugai sought injunction against generic drug manufacturers based on infringement of the Patent.

As of August 10, 2015, Chugai filed a lawsuit with the Tokyo District Court against Iwaki Seiyaku Co., Ltd., Takata Pharmaceutical Co., Ltd., and Pola Pharma Inc. (hereinafter collectively referred to as "3 companies"), manufacturers of generics of OXAROL Ointment, seeking compensation for damages for infringement of the Patent. The Tokyo District Court rendered a judgment today. The details of the judgment are as follows.

1. Content of the Judgment on the Suit for Damages for the Patent Infringement

The three generic drug manufacturers were determined to be liable for damages, and the following payments were ordered.

- 1) Defendant Iwaki Seiyaku Co., Ltd.: Payment of 203,632,798 yen and payment of five percent a year in interest from September 15, 2015 until completion of payment to the plaintiff, Chugai Pharmaceutical Co., Ltd. (hereinafter referred to as Plaintiff)
- 2) Defendant Takata Pharmaceutical Co., Ltd.: Payment of 118,159,458 yen and payment of five percent a year in interest from September 15, 2015 until completion of payment to the Plaintiff
- 3) Defendant Pola Pharma Inc.: Payment of 168,223,686 yen and payment of five percent a year in interest from September 15, 2015 until completion of payment to the Plaintiff
- 4) Defendant Iwaki Seiyaku Co., Ltd., defendant Takata Pharmaceutical Co., Ltd., defendant Pola Pharma Inc.: Jointly, payment of 579,169,686 yen and payment of five percent a year in interest from September 15, 2015 (of which 179,169,686 yen, from September 1, 2016) until completion of payment to the Plaintiff

Chugai's OXAROL Ointment and OXAROL[®] Lotion were eligible for the pricing premium for the promotion of new drug development and the elimination/resolution of off-label use in drug price calculations, however, with the entry of the generics of OXAROL Ointment, the prices of both OXAROL Ointment and OXAROL Lotion were reduced in the amount of the premium earlier than the originally scheduled date. This is the first instance of a judgment regarding damages incurred by a manufacturer of brand-name drugs due to reduction of drug prices in the amount of the drug price premium, and 4) above is an assessment of the liability of the three generic drug manufacturers for the reduction of the drug prices of OXAROL Ointment and OXAROL Lotion in the amount of the drug price premium. Payments 1) to 3) above are an assessment of the liability of the respective generic

drug manufacturers for damages incurred by Chugai due to the loss of sales of Chugai's OXAROL Ointment from the sale of infringing products by the respective generic drug manufacturers.

2. Regarding the Response Going Forward, etc.

Chugai's response going forward and the impact of this lawsuit on the business performance will be determined upon close examination of the content of the judgment.

<Reference: Background of the Infringement Lawsuit Injunction>

1) As of February 19, 2013, Chugai filed a lawsuit with the Tokyo District Court against the 3 companies and DKSH Japan K.K., an importer of the active ingredient of these generic products, seeking injunction based on infringement of the Patent.

2) As of March 24, 2017, the Supreme Court rendered a judgment dismissing the appeal by the generic drug manufacturers and the active ingredient importer, finalizing Chugai's victory.